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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,205

Applicant(s)

SIA ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 16-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-19 are currently pending in the instant application. The claims have been subject to restriction as set forth below.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15 and 19, drawn to vectors encoding an extracellular fragment of gp140 of a primary HIV isolate, immunogenic compositions comprising the vectors and methods of generating a CTL response to HIV by administering the immunogenic composition comprising the vector.

Group II, claim(s) 16-18, drawn to a peptide having an amino acid sequence selected from a group consisting of SEQ ID NOS: 3-14.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the nucleic acids of invention I are substantially different in physical, chemical, and biological properties than the peptides of invention II. Further, the nucleic acids of invention I do not require the peptide of invention II for its production or use and vice versa. Finally, peptides according to group II were known in the prior art, see for instance WO 93/18055. Thus, for all the above reasons, the inventions do not share a same or corresponding special technical feature.

During a telephone conversation with Michael Stewart on 2/10/05 a provisional election was made without traverse to prosecute the invention of group II, claims 16-18 directed to peptides. Affirmation of this election must be made by applicant in replying to this Office

action. Claims 1-15 and 19 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim 16-18 are therefore currently under examination in the instant application. An action on the merits follows.

Priority

Applicant has not fully complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 or 365(c) as follows: while the specification contains a paragraph on page 1 of the specification which claim benefit of priority to parent application 09/256,194, the status of the 09/256,194 application has not been amended to reflect the issuance of this application as U.S. Patent No. 6,395,714 on 5/28/02. Further, the priority reference does not appear as the first sentence on page 1, after the title.

If applicant desires benefit of a previously filed application under 35 U.S.C. 120, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. **This should appear as the**

first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. **The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression “now Patent No. _____” should follow the filing date of the parent application.** If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under

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37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

The disclosure is objected to because of the following informalities: the brief description of Figure 2 on page 3 of the specification does not match Figure 2 in the drawings in that the drawings show figures 2A-2E. Applicant can overcome this objection by amending the brief description of the drawings on page 3, lines 25, to read " Figures 2A-2E show ...".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/18055 (September 1993), hereafter referred to as Berzofsky et al. The applicant claims a peptide having an amino acid sequence selected from a group consisting of SEQ ID Nos: 3-14 (claim 16). The applicant further specifically claims said peptide having SEQ ID NO:3 (claim 17).

Berzofsky et al. teaches an isolated polypeptide having an amino acid sequence selected from a group which includes IGPGRAFYTT (Berzofsky et al., page 43, claim 3). Please note that IGPGRAFYTT is identical to SEQ ID NO: 3 of the instant application. Thus, by teaching all the limitations of the claims as written, Berzofsky et al. anticipates the instant invention as claimed.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Verrier et al. (August, 1997) PNAS, Vol. 94 (17), 9326-9331. The applicant claims a peptide having an amino acid sequence selected from a group consisting of SEQ ID Nos: 3-14 (claim 16). The applicant further specifically claims said peptide having SEQ ID NO:3 (claim 17), or SEQ ID NO:5 (claim 18).

Verrier et al. teaches the polypeptide envelope protein from the primary HIV isolate BX08 (Verrier et al., page 9327-9328). Please note that the claims as written use the term “having” which is broad claim language similar in scope to “comprising”. As such, the peptides of claims 16-18 are not limited to the nonamers listed as SEQ ID NO: 3-14, but encompass any polypeptide which contains at least one of these sequences. The peptides of SEQ ID NOS: 3-14 of the instant invention are derived from the envelope of the primary HIV isolate BX08. Therefore, the BX08 envelope polypeptide inherently comprises the nonamer sequences claimed, including specifically SEQ ID NO:3 and SEQ ID NO:5. As such, Verrier et al. anticipates the instant invention as claimed.

Claims 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,976,541 (11/2/99), Berzofsky et al., hereafter referred to as the ‘541 patent. The applicant claims a peptide having an amino acid sequence selected from a group consisting of SEQ ID Nos: 3-14 (claim 16). The applicant further specifically claims said peptide having SEQ ID NO:3 (claim 17).

The ‘541 patent teaches an isolated polypeptide consisting of the amino acid sequence IGPGRAPHYTT (‘541 patent, column 37, claim 2). As noted above, IGPGRAPHYTT is identical to SEQ ID NO: 3 of the instant application. Thus, by teaching all the limitations of the claims as written, the ‘541 patent anticipates the instant invention as claimed.

Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,534,482 (2/18/03), hereafter referred to as Fikes et al. The applicant claims a peptide having an amino acid sequence selected from a group consisting of SEQ ID Nos: 3-14.

Fikes et al. teaches a peptides with the sequence KLTPLCVTL (Fikes et al., column 51, Table 6, SEQ ID NO: 326). KLTPLCVTL is identical to SEQ ID NO: 10 of the instant application. Thus, by teaching all the limitations of the claim as written, Fikes et al. anticipates the instant invention as claimed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 9:30-6:00 EST. If the examiner is not available, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735. For all official communications, **the new technology center fax number is (571) 273-8300**. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

